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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,967

02/27/2004

Joseph Anthony Gatto

8725R2R

9429

27752 7590 04/27/2010
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EXAMINER

PAGONAKIS, ANNA

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

04/27/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/789,967	Applicant(s) GATTO, JOSEPH ANTHONY	
	Examiner ANNA PAGONAKIS	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 and 20-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18 and 20-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed 1/14/2010 has been received and entered into the present application.

Applicant's arguments filed 1/14/2010 have been fully considered. Rejections are not reiterated from previous Office Actions are hereby withdrawn. The following rejections are reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Priority

This application claims benefit of 10/444,241 filed 5/23/2003; 10/152,924 filed 5/21/2002 and 09/968,154 filed 10/1/2001.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, 10/444,241 filed 5/23/2003; 10/152,924 filed 5/21/2002 and 09/968,154 filed 10/1/2001, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. All claims are not adequately supported or enabled by the prior-filed applications for a method for preparing a lotion comprising the steps of (a) providing a carrier system; (b) mixing a premix comprising niacinamide and a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof, at a temperature of at least about 35 degrees Celsius and (c) milling the premix solution into the carrier system at a temperature of at least about 35 degrees Celsius to disperse the premix solution until an

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average droplet diameter of the dispersed premix solution is less than about 100 microns to form said lotion.

It is noted that Applicant is not entitled to the priority date in these application for all claims in the instant claim set because the information contained within the previous referred filings does not support the granting of an earlier filing date.. There is no instance, throughout the specification, of any calculation of any ratio. **All claims are given a priority date of February 27, 2004.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-18 and 20-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “at least about” and “less than about” are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack clarity as to whether "from" (a lower limit) or "about (broadening limitation, both higher and lower) controls the metes and bounds of the phrase "from about." Regarding "at least" (a lower limit) or "about" (broadening limitation, both higher and lower) it is unclear what controls the metes and bounds of the phrase “at least about.” Regarding "less than (a lower limit) or "about" (broadening limitation, both higher and lower) it is unclear what controls the metes and bounds of the phrase "less than about."

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Claims 11-18 and 20-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The term "at least about" and "less than about" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack clarity as to whether "from" (a lower limit) or "about" (broadening limitation, both higher and lower) controls the metes and bounds of the phrase "at least about." Regarding "less than (a lower limit) or "about" (broadening limitation, both higher and lower) it is unclear what controls the metes and bounds of the phrase "less than about."

Response to Applicant's Remarks

Applicant continues to contend that the above claim terms are commonly used in defining numerical ranges, especially in the chemical arts. This is not found persuasive. As noted previously, Applicant has failed to provide a definition for the term "about" in the instant specification, such as there is no indication or hint as to what amount of variation above or below the recited temperature and droplet diameter would constitute infringement of the instant claims. There is nothing in the specification or prosecution history that provides any indication as to what amount of variation is tolerated by the term "about."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 11-16 and 20-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Scavone (WO 02/069924) and Osborne et al. (U.S. 6,716,441, of record).

Scavone teaches a method of preparing a lotion such as an antiperspirant or deodorant composition comprising vitamin B3 derivatives such as niacinamide and low concentrations of glycerin (page 3, lines 1-4 and page 7, line 23). This product is milled under ambient conditions for a period of time sufficient to reduce and break up any agglomerates of solid skin care active or solid antiperspirant active such that no agglomerates are present at a size greater than 10 microns (Example 4, page 18).

Scavone et al. is silent on the use of a carrier such as petrolatum.

Osbourne et al. teach an effective delivery of a therapeutic skin care active to the skin via a novel release composition which is preferably incorporated into a dispensing means. Petrolatum is a carrier typically used to provide a long-lasting coating (column 1, lines 66-67). The composition further comprises chitosan, panthenol and vitamin C. Skin actives include calamine, cysteine hydrochloride, racemic methionine, sodium bicarbonate, vitamin C (column 5, lines 33-38) and talc (column 15, lines 55). Suitable solvents include propylene glycol and glycerines (column 16, line 28).

One of ordinary skill in the art would have been motivated to use petrolatum as a carrier in the method of preparing a lotion by milling at ambient conditions as taught by Scavone et al. because petrolatum as per Osborne et al. is a well known effective carrier in lotions.

“[W]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro., 425 U.S. 273, 282 (1976). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise

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teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

Note: MPEP 2144.04 [R-1] Changes in Sequence of Adding Ingredients: Ex parte Rubin , 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render *prima facie* obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scavone (WO 02/069924) and Osborne et al. (U.S. 6,716,441) as applied to claims 11-16 and 20-25 above, and further in view of Sharma et al. (U.S. 5,104,913).

The combination of Scavone (WO 02/069924) and Osborne et al. (U.S. 6,716,441) is silent on the use of an average particle size of about 2 microns.

Sharma et al. teach that milling of a composition including propylene glycol and petrolatum can produce particles typically having average particle size of about 2 microns (column 6).

One of ordinary skill in the art would have been motivated to use a milling as a means of reducing the micron size of the particles because it is known in the art that milling can produce a particle size of about 2 microns.

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Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scavone (WO 02/069924) and Osborne et al. (U.S. 6,716,441) as applied to claims 11-16 and 20-25 above in view of Kelly (U.S. 5,264,205).

The combination of Scavone (WO 02/069924) and Osborne et al. (U.S. 6,716,441) is silent on the milling temperature being below 50 degrees Celsius.

Kelly teaches that milling of a composition is done at a temperature of below 50 degrees Celsius (column 3).

One of ordinary skill in the art would have been motivated to mill the composition at a temperature of about 50 degrees Celsius because it is known that composition are effectively milled at this temperature.

Further, the determination of optimum temperature is well within the skill of the artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan.

Response to Applicant's Remarks

Applicant alleges that Osborne discloses a long list of suitable skin care actives to be incorporated into its release compositions. Applicant appears to be of the persuasion that, because Osborne et al disclose suitable skin care actives in addition to the one instantly elected, this somehow constitutes a complete lack of teaching of the claimed skin care active and/or constitutes a teaching away from the instantly claimed skin care active. This is not persuasive. A preferred or exemplified embodiment does not constitute a teaching away from other embodiments disclosed within the four corners of the reference, including non-preferred embodiments. Applicant is reminded that the disclosure of a reference must be considered as expansively as is reasonably possible to determine the full scope of the disclosure and, as a result, is most certainly most limited to that which is preferred and/or exemplified.

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Thus, the fact that other suitable skin care actives may be exemplified, claimed and/or preferred does not negate or direct the artisan away from the broader teaching of the reference, which expressly provides for, and, thus, clearly contemplates the use of, the instantly claimed skin care active to those within the genus of skin care actives instantly claimed. The fact that the reference may teach embodiments that differ from Applicant's own invention does not negate, or teach away from, the teachings of the reference as a whole and what the reference as a whole would have reasonably suggested to one having ordinary skill in the art at the time of the invention. Further, picking and choosing elements from a reference, that differ from those upon which the Examiner relies in support of the rejection as a means for discounting the anticipate made by the Examiner is not persuasive when Applicant does not clearly acknowledge and address the pertinent teachings of the reference upon which the rejection is based, specifically, the disclosure found in Osborne et al, which clearly teaches the instantly claimed skin care active discussed in the body of the previous rejection.

Applicant alleges that Osborne et al. teaches that the two alternative methods of incorporating of incorporating its skin care actives into its release compositions in contrast to the instantly claimed method. This is not found persuasive. Applicant is again reminded that rejections made under 35 U.S.C. 103(a) are based upon the combination of references. As a result, focusing solely on the discrete teachings of each of the cited references is tantamount to examining each of them inside of a vacuum and fails to be persuasive in establishing non-obviousness because it is the *combined* teachings that are the basis for a proper conclusion of obviousness, not each individual reference alone. In other words, it must be remembered that the references are relied upon in combination and are not meant to be considered separately. To properly conclude obviousness of an invention *does not require the claimed invention to be expressly suggested in its entirety by any one single reference under 35 U.S.C. 103(a).* Rather, the test is *what the combined teachings* of the references would have suggested to those of ordinary skill in the art.

Conclusion

No claim is found to be allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642